

US EPA ARCHIVE DOCUMENT

From Scott P Carroll <spcarroll@ucdavis.edu> 12/19/2006 04:46 PM
To John Carley/DC/USEPA/US@EPA
cc
bcc
Subject Re: Reports on EMD-003 and EMD-004

That correspondence is attached, John.

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30 October 2006

Kim Lerner
IIRB

Dear Kim,

We submit (via email) the revised insect repellent test protocols (with ICFs) EMD-003 and EMD-004 for your expedited review.

Thank you very much.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott P. Carroll". The signature is fluid and cursive, with the first name "Scott" and last name "Carroll" clearly distinguishable.

Scott P. Carroll
Director

Email cover letter accompanying the submission of revised protocols described above:

In response to HSRB comments, in ICF EMD-003 I have eliminated the mention of compensation as a benefit (that must have remained in as an editing error) and likewise the mention of medical information disclosure in the consent and signatures section, as that is not relevant. I have added lactation to the restrictions in the pregnancy section. In addition, under research related injuries, we now include a statement that a consulting physician will be contacted. Lastly, I have responded to their suggestions to indicate that "There is a small possibility..." of risks/discomforts from the test material alcohol, etc. They thought the risks were overemphasized without such a modifying clause.

All of these changes are highlighted on-screen in EMD-003, and can be called up in EMD-004. If I just attach Word versions of the revised docs, is that enough for you to consider the changes? I will start in that way.

Please let me know what you think. I am sorry that this has had to become such a custom/pet project, but it has indeed remains pleasure to team with you in its creation, conduct and coordination.

Best,
Scott